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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,710	10/03/2003	Arthur M. Krieg	C1039.70074US00	9983

7590 10/29/2007  
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Boston, MA 02210

EXAMINER
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HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/679,710	Applicant(s) KRIEG ET AL.	
	Examiner Michelle Horning	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-47, 52 and 94-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-47, 52 and 94-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                       |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

This office action is responsive to communication filed 8/16/2007. The status of the claims is as follows: claim 45-47, 52 and 94-100 are under current examination.

#### ***Information Disclosure Statement***

The IDS was considered in its entirety.

#### ***Claim Rejections - 35 USC § 112-MAINTAINED***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 45-47, 52 and 94-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement was considered in view of the *Wands* factors (MPEP 2164.01(a)).

Applicants' arguments were considered but not found to be persuasive. The arguments made by Applicants are addressed below as well as some points the Applicants have failed to address.

First, the Office would like to remind the Applicants of the nature of the invention. The invention is drawn to a *method of treating or eliminating a tumor or cancer in a*

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*subject with an immune system deficiency.* Applicants state that Applicants have taught “oligonucleotides containing an unmethylated CpG dinucleotide produce an immune response that is consistent with the treatment of cancer”. While changes in the immune responses have been characterized, including B-cell proliferation, IgM secretion, induction of TNF-alpha, etc. etc., the specification provides no support for such a correlation and how the claimed method would lead to the successful treatment or elimination of a tumor or cancer in any subject, including those with an immune system deficiency.

Please note the breadth of the claims. As discussed in the previous Office Action filed 2/13/2007, the claims are extremely broad and encompass tumors and cancer of all types and they may include brain tumors, ovarian cancer and malignant haematological diseases as only a few examples. The working examples in the specification demonstrate the immune effects of ODNs on B cells isolated from mice spleens but they do not demonstrate a successful *method of treating or eliminating a tumor or cancer in a subject with an immune system deficiency*. The specification fails to support a correlation between the working examples and claimed methods.

Additionally, with respect to Bodey et al, Applicants submit that the “constant microevolution” is described in the context of vaccine therapies based on tumor antigens. The argument has been shifted. Bodey et al recites the following “Malignant tumors undergo constant microevolution” (see page 2673). Given that malignant tumors are ever changing for example, the ordinary artisan cannot predict which ODNs to make/use in performing a method of treating or eliminating a tumor in a subject with an

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immune system deficiency. The constant microevolution is not addressed in the specification.

Applicants state the following: "It is unclear to Applicants why the experimentation required to perform the method would be considered to be undue". In response, the specification fails to support a *method of treating or eliminating a tumor or cancer in a subject with an immune system deficiency*.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

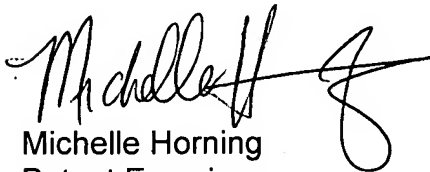
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michelle Horning  
Patent Examiner



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